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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/009,384

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Maria Laura Gennaro

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07/21/2008

PATENT DOCKET ADMINISTRATOR

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/009,384

Applicant(s)

GENNARO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 14 April 2008, is acknowledged. Claims 1, 2, , 12, 15, 16, 18, 19, and 20 have been amended.
2. Claims 1-8 and 11-20 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Walker et al (U.S. Pat. No. 5,736,365, 7April1998), is withdrawn in light of the claim amendment.
4. The rejection of claims 2, 4, 6, 8, 12, 14, 15, 16, 18, 19, and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for "specific antigenic property", is withdrawn in light of the amendment of the claims.
5. The rejection of claims 2-8 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is withdrawn.

Rejections Maintained

6. The rejection of claims 17-20 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnostic methods utilizing polypeptides, is maintained.

Applicants argue that the instant specification does enable the claimed invention by: 1) teaching specific sequences of the claims, 2) identifying such sequences as encoding for secreted polypeptides, 3) teaching that secreted proteins are effective as antigens capable of inducing protective immunity to an organism, and 4) teaches working examples of serologic immunoassays used to detect immune response to polypeptides of *M. tuberculosis* (U.S. Pat. No. 6,087,163).

The examiner has considered applicants' argument, but does not find it persuasive. As stated in prior Office Actions, the instant specification contains no working examples of methods

for detecting *M. tuberculosis* infected hosts or hosts susceptibility to *M. tuberculosis* utilizing the listed polypeptides or any other compositions. The specification merely contains computer generated sequences of *M. tuberculosis* DNA and predicted *M. tuberculosis* proteins, and U.S. Pat. No. 6,087,163 does not teach immunoassays utilizing the specific sequences of the instant claims. Thus, there is not sufficient support for the claims, i.e., a method of determining that a subject has a *M. tuberculosis* infection by utilizing the claimed sequences.

Applicants argue that where a whole polypeptide has been identified as likely to produce a desired antigenic response, it would not constitute undue experimentation to further identify segments of the polypeptide which are also likely to produce the desired antigenic response.

The examiner has considered applicants' argument, but does not find it persuasive. While determination of segments with a desired application may not be undue experimentation, such a determination is based upon a foundation that the whole polypeptide functions as required. As shown above, the specification merely contains computer generated sequences of *M. tuberculosis* DNA and predicted *M. tuberculosis* proteins, and U.S. Pat. No. 6,087,163 does not teach immunoassays utilizing the specific sequences of the instant claims. Thus, there is no foundation for the enablement of segments because there is insufficient support for methods utilizing the whole polypeptides in question.

7. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Horwitz et al (U.S. Pat. No. 5,108,745, 28 April 1992), is maintained.

Applicants argue that Horwitz et al do not teach each and every element of the claim, i.e., 1) a polypeptide, that is 2) isolated, and 3) has an amino acid sequence selected from a group of six enumerated sequences.

The examiner has considered applicants' argument, but does not find it persuasive. According to the specification, by definition, MTSP means "*M. tuberculosis* secreted protein". The proteins taught by Horwitz et al are the *M. tuberculosis* secreted proteins. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *in re* Best, 562 F.2D 1252, 195 USPQ 430 (CCPA 1977), and *in re* Fitzgerald et al., 205 USPQ 594.

Thus, in the absence of evidence to the contrary, the *M. tuberculosis* secreted proteins taught by Horwitz et al are identical to the *M. tuberculosis* secreted proteins of the instant claim.

8. The rejection of claims 12-16 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is maintained.

Conclusion

9. Claims 11-20 are finally rejected.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

July 7, 2008

Application Number**Application/Control No.**

10/009,384

**Applicant(s)/Patent under
Reexamination**

GENNARO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645